SOP 18
SUBCOMMITTEE ON RESEARCH SAFETY (SRS)

1.0 PURPOSE AND SCOPE

1.1 This SOP specifies the responsibilities and requirements for the establishment of the Subcommittee on Research Safety (SRS) at the VAMC Research Service, Charleston, SC. ***This SOP is applicable to the Charleston, SC VAMC Research Service only.***

1.2 The provisions of this SOP apply to all research that is conducted completely or partially in VA facilities, conducted in approved off-site locations and facilities, or conducted by VA researchers while on VA official duty time.

2.0 RESPONSIBILITIES

2.1 The VA Medical Center Director shall ensure that the research safety program is adequately staffed and resources are available to maintain full compliance with all applicable regulations and standards of safety. The Director shall ensure that all research office personnel are included in the facility Occupational Safety and Health program. Personnel must be covered by all other facility safety programs (e.g., Respiratory Protection Program, Bloodborne Pathogens Program, Chemical Hygiene Program, etc.).

2.2 The ACOS/R&D shall ensure that safety-related communications from the Chief Research and Development Officer (CRADO) are disseminated to appropriate personnel in a timely manner after receipt. The responses to safety "holds" are the responsibility of the ACOS/R&D, as is the responsibility to assure that research activity ceases until a particular "hold" is lifted. The research safety program must be continuously evaluated according to performance standards developed by the ACOS/R&D.

2.3 The R&D Committee shall establish either an SRS or multiple subcommittees dealing with different aspects of research safety. In some instances, alternate safety oversight and review mechanisms may be developed with an affiliate safety committee or committees that will perform all VA mandated functions. Pre-approval by the CRADO is required to use this mechanism. This alternate mechanism does not absolve the R&D Committee from any responsibilities related to the functions of the SRS. If using the services of an external subcommittee, VA interests must be adequately represented by the inclusion of at least one VA employee with appropriate qualifications.

3.0 REQUIREMENTS

3.1 The R&D Committee shall perform the following:

1) Review all R&D proposals and ensure SRS review of those protocols/submissions for funding that involve safety hazards to personnel and/or the environment.

2) Act upon SRS recommendations for approval or non-approval of reviewed proposals for submission to VA Headquarters.

3) The R&D Committee shall review and act upon SRS minutes.

4) Appoint a Research Safety Coordinator who is responsible for supervising and operating the Research Safety Program. The ACOS/R&D will generally assume this role.

5) Appoint a Biological Safety Officer if research is conducted at the facility involving the use of recombinant deoxyribonucleic acid (DNA) at BSL 3 or 4, or large scale (greater than 10 liters of culture) research or production activities involving viable organisms containing recombinant DNA molecules. This may require the establishment of an Institutional Biosafety Committee (IBC).

6) Oversee and ensure research PI/study team compliance with this SOP.

7) Ensure the development and implementation of safety protocols by the PI for individual research projects as needed.

8) Assure that the VA Research Service provides support to the SRS.

9) Ensure the minutes of SRS meetings are documented correctly and maintained by the VA Research Service.

10) Provide the ACOS/R&D, facility, or VISN safety officials with adequate information to evaluate the performance of the R&D safety program.

3.2 The SRS shall perform the following:

1) Perform and maintain documented review of all new research proposals involving biological, chemical, physical, and radiation hazards submitted via the mandatory Research Protocol Safety Survey, VA Form 10-0398 (Appendix F of the VHA Handbook 1200.8). The proposals will be reviewed for compliance with all applicable regulations, policies, and guidelines pertinent to biological, chemical, physical, and radiation hazards prior to submission for R&D review and approval. The review of the mandatory Research Protocol Safety Survey, VA Form 10-0398 (Appendix F of the VHA Handbook 1200.8) shall include a risk assessment of the facilities, level of containment, laboratory procedures, practices, training and expertise of personnel involved in the specific research conducted including recombinant DNA research. Provide written notification of the SRS review results to the PI, the R&D Committee, and the PIs R&D research folder.

If a protocol is submitted to the SRS on VA Form 10-0398 but does not involve the use of any biological hazards (i.e., all responses = "NO"), the protocol will still require review by the SRS. The SRS shall confer "SRS EXEMPT" status upon the protocol. The protocol will not require future review by the SRS unless the protocol is modified to include any safety hazards. The SRS shall report the results of review of the protocol to the PI and to the ACOS.

2) Projects that are submitted to the SRS and request guidance pertaining to the need for an SRS review will be reviewed administratively by the SRS Coordinator and/or Chair. A determination will be made regarding the need to submit a formal VA Form 10-0398 for that individual specific project and the PI will be notified of this decision. If the SRS

administrative review determines that the research project does not involve safety hazards, the SRS membership will be informed of the results of this administrative review at the next convened SRS meeting. If the project is subsequently modified to include any type of associated biological, chemical, physical or radiation hazards, then the PI must submit a VA Form 10-0398 to the SRS for formal review and approval.

3) Perform and maintain documented annual reviews of all active research protocols involving biological, chemical, physical, and radiation hazards regardless of funding status or source. Annual reviews submitted to the SRS will be reviewed by the SRS Coordinator and/or Chair. A summary of the findings will be reported to SRS members at the next convened SRS meeting. The date of continuing review is based on the date of SRS approval. Changes in the research protocol not included in the original application must be documented by submitting an amended Research Protocol Safety Survey, VA Form 10-0398 (Appendix F of the VHA Handbook 1200.8) or the Subcommittee on Research Safety (SRS) Biosafety Annual Project Review Package to the SRS for approval prior to the implementation of the changes. If utilizing the SRS Biosafety Annual Project Review Package, a copy of all modified forms must also be included and submitted for review by the SRS. Provide written notification of the results of the SRS review to the PI.

4) All projects/protocols that have been closed, withdrawn or terminated must be officially terminated with the SRS.

5) Coordinate all safety-related activities in research laboratories including safety training, safety inspections, accident reporting, and liaison activities with all facility safety committee and officials.

6) Report operational problems or violations of directives to the Research Safety Coordinator within 30 days of occurrence or detection unless the SRS determines that the PI has previously filed a report.

7) Identify the need for health surveillance of personnel involved in individual research projects and if appropriate, advise the R&D Committee and Employee Health Practitioner on the need for such surveillance.

8) Maintain adequate documentation of all SRS or equivalent subcommittee activities.

9) Forward minutes to SRS committee members and the R&D Committee.

10) Assure all laboratory personnel receive documented research-specific training.

11) Hold SRS meetings at least quarterly.

12) Inspect each laboratory for compliance with safety requirements at least on a semi-annual basis.

13) Conduct on at least a semi-annual schedule, drills to evaluate the ability of laboratory personnel to resolve a:

- Chemical spill

- Biologic spill
- Presence of an unauthorized intruder

Drills will coincide with the semi-annual inspection of the research laboratories by the SRS.

The results of each drill will be recorded and discussed at the next convened meeting of the SRS. A summary report of the drill will be available for review at the next convened meeting of the R&D Committee.

14) Because VA laboratory space in the Strom Thurmond Building is leased from the Medical University of South Carolina (MUSC), VA laboratories in the Strom Thurmond Building will follow MUSC policies for:

- Chemical Hygiene Plan
- Fire Reaction Plan
- Ethylene Oxide management Plan
- Blood-Borne Pathogens Plan
- Bomb Threat Policy
- Guidelines for Laboratory Use of Chemical Carcinogens
- Hazard Communication Plan
- Microwave Policy
- Policy for Administration of Hazardous Pharmaceutical Aerosols
- Respiratory Protection Program Policy
- Spill Prevention and Counter measures Plan
- Work practice Policy for Personnel Dealing with Cytotoxic/Antineoplastic Drugs
- Active Shooter Emergency Plan
- Emergency Response and Evacuation Procedures

The SRS annually will review and evaluate the above described MUSC policies and collectively vote on their continued use by SRS at the January meeting of the SRS.

The SRS will continue to follow VA policy for the following:

- Supplemental Emergency Preparedness Plan (CPM 151-07-01)
- Research Service Hurricane Preparedness Plan
- Emergency Showers, Eye Washes, Combination Shower Plus Eye Wash Units, and Hand-Held Drench Hose Testing plan (CPM 138-09-01)
- Employee Tuberculin Skin Testing Program (CPM 11E-07-06).

3.3 The PI shall perform the following:

1) Submit a completed Research Protocol Safety Survey, VAF 10-0398 (Appendix F of the VHA Handbook 1200.8) along with each research proposal to be submitted for funding. The SRS shall review the proposal and safety survey form. Any protocols that have been "tabled" by the SRS because significant deficiencies were identified will be required to include a cover letter whenever the protocol is again submitted to the SRS. This letter must detail the PIs

response to each deficiency identified by the SRS in the original application. If the PI fails to adhere to the above policy at the time the protocol is again submitted to the SRS for review, the application will again be "tabled" until the SRS receives the required cover letter. Should a protocol be "tabled" a total of two times, in the interest of time and laboratory safety, the SRS may administratively withdraw the protocol until all SRS requested requirements are satisfactorily met.

2) Assure that all new protocols and new pilot projects involving biological, chemical, physical, and radiation hazards have a documented review by the SRS.

3) Immediately notify the SRS if the project is closed, withdrawn, terminated, or if the project status or the role as PI in the project changes.

4) Identify laboratory specific hazards and assure that all personnel receive training specific to the hazard(s). Advise laboratory personnel of any potential risk to themselves or the research environment.

5) Supervise the performance of laboratory staff to ensure the correct use of required safety practices and techniques, including the use of personal protective equipment.

6) Assure that biological safety cabinets are certified annually. In research settings involving airborne pathogens, certification must be performed on a semi-annual basis.

7) Report problems and concerns about the operation and containment practices and procedures to the Research Safety Coordinator, facility safety officer, Veterinary Medical Officer, Radiation Safety Officer, and other appropriate authorities.

8) Assure that all accidents are reported to the Employee Health Office and the facility safety office.

9) Secure approval of the R&D Committee through the SRS for any significant changes made in the original research plan that include the use of any biological hazards, human/non-human tissues, recombinant DNA, chemicals, controlled substances, or ionizing/non-ionizing radiation.

10) Remove all chemicals, biological agents, radioisotopes, and waste generated by these materials prior to leaving or relocating the research space.

4.0 INFRASTRUCTURE OF THE SRS

4.1 The SRS shall include members from the facility safety committee, such as the Safety Officer or the Facility Infection Control Committee, the IACUC, the Radiation Safety Office (RSO), and a liaison from the affiliated university Institutional Biosafety Committee. Such individuals may be included in the core five members of the SRS.

4.2 Each SRS shall have at least five members, exclusive of ex-officio members. The SRS will include two members not affiliated with the VA Medical Center, when the research reviewed

involves DNA not exempt from the current National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules.

4.3 The SRS usually will posses expertise in the following:

1) Etiologic agents, including bloodborne and airborne pathogens.

2) Chemical carcinogens and other chemical hazards.

3) Physical and radiation hazards.

4) It is highly desirable that the Veterinary Medical Officer (VMO) or a member of the IACUC be appointed to the SRS.

4.4 The following are ex-officio members of the SRS:

1) The ACOS for R&D (non-voting).

2) The AO for R&D (non-voting).

3) A liaison member from local the R&D Committee (voting).

4) An employee union safety representative or other union designee whose voting status is determined by the applicable union contract.

4.5 The following are Consultants to the SRS:

1) The Research Compliance Officer (non-voting).

4.6 Appointment of Members: SRS forwards the nominee names along with their specified length of appointment for SRS membership to the Medical Center Director. The Medical Center Director must officially appoint members in writing.

4.7 Chairperson: The SRS Chairperson shall be appointed by the Medical Center Director for a term of one (1) year and may be re-appointed without any lapse in time. There is no limit to how many times a Chairperson may be reappointed, but it is a best practice to rotate the Chairperson position to develop a cadre of research staff at each institution with the experience of filling the Chairperson's role. The SRS Chairperson shall not simultaneously chair the R&D Committee or another subcommittee thereof.

4.8 Length of Terms: Members other than those who are designated ex officio (appointed on the basis of their position) may serve terms of up to three (3) years. Members may be re-appointed without lapse in service to the SRS.

4.9 Role of the Chairperson: The SRS Chairperson's responsibilities include the following:

1) Lead each SRS meeting.

2) Communicate with Research Service staff and other Charleston VAMC personnel on behalf of the SRS.

3) Perform administrative actions on behalf of the SRS such as signing submitted protocols, audit responses, project transfers, inspection deficiency follow-ups, etc.

4) Reports SRS actions to the R&D committee.

5) In the absence of the Biological Safety Officer (BSO), the SRS chairperson will act as the Chemical Hygiene Officer for the VA Research Service.

5.0 If research with recombinant Deoxyribonucleic Acid (rDNA) is conducted in the VA Research facilities, then it shall comply with all requirements with respect to composition of an Institutional Biosafety Committee as specified in the NIH Guidelines.

5.1 Submission of the VA IBC SRS annual report in a timely manner to the NIH OBA (Office of Biotechnology Activities) for review and approval. The SRS annual report is due to the OBA on or before the anniversary of the previous year's annual report date.

5.2 An agenda should be developed before each meeting of the SRS and distributed to members at least 3 working days before the meeting whenever possible. At a minimum, the agenda should include the following:

1) Minutes of the previous months convened SRS meeting.

2) Unfinished business. List pending items and individual responsible.

3) New business. Identify responsible individual when necessary.

   a. Standing recurring reports. Identify responsible individual.

   b. Issues. Any issues not previously addressed by the body.

   c. Other. Any other item(s) that warrant(s) review or discussion by the SRS and is not routinely reviewed by the committee.

4) Announcements.

5) Date, time, and place of the next meeting.

5.3 Minutes of all SRS meetings shall be recorded. The minutes shall document the attendance or absence of members and provide a complete record of all items of business or information brought before the committee. Motions presented to the committee shall be recorded verbatim to include the action(s) taken by the SRS. Votes on motions shall be reported to indicate whether the action is unanimous or by divided vote with a statement of the number of members voting for and against the motion. Minutes of all SRS meetings shall be recorded in the following format:

1) Identification of the subcommittee to be centered at the top of the page, including VA medical center name and number.

2) The first paragraph should include:

   a. Place, date, and time of the meeting.

   b. Name of presiding officer (SRS Chairperson).

   c. List of attendees. The attendance record will list all individuals identified as members. Members will be marked **ABSENT** if the Chairperson or Recorder has not been notified in advance. Members will be marked **EXCUSED** if the Chairperson or Recorder was notified in advance.

3) Succeeding paragraphs should identify the recommendations, date of the meeting when the recommendation was initially made, action taken to date or a realistic date to expect resolution, and the status as **CLOSED** or **PENDING**.

   NOTE: *A recommendation should not be carried for more than 2 meetings awaiting a resolution. Otherwise, there must be clear documentation that a plan of action is being followed and an anticipated date for resolution is noted.*

4) Minutes shall not be recorded verbatim except for recommendations. The substance of the discussion shall be reported clearly and concisely. After summation of the discussion, the minutes shall reflect:

   a. **Conclusion.** What was concluded from the discussion? (Example: "The follow-up action plan was ineffective, and the issue is not considered resolved at this time."). If analysis of the data occurred in the meeting, then the conclusion of the analysis should be in the minutes.

   b. **Recommendation.** Include who and/or what is expected to change and the person responsible for implementing the action.

   c. **Action.** Include what action is appropriate in view of the cause, scope, and severity of the problem and who is responsible for implementing the action.

   d. **Follow-up or Evaluation.** Identify the date a status report is due on the action plan, the date the action plan will be implemented, or the date the action plan will be evaluated for accomplishment of expected outcome/impact of changes made.

5) SRS members having a scientific or monetary conflict of interest for the protocol under consideration may provide information helpful to the SRS prior to deliberations, but must excuse themselves from the meeting once deliberations begin.

6) Minutes shall be written and published within three weeks of the meeting date.

7) Minutes shall be signed by the SRS Chairperson and the VAMC Director.

8) Approved minutes shall be forwarded to the R&D Committee for review and approval. The R&D Committee may review the minutes for content regarding committee functions, protocol review, education of members, and preparation of minutes. Recommendations for changes or improvements in SRS procedures may be made, but the R&D Committee may not alter the SRS minutes.

9) Minutes shall be maintained by the VA Research Service and made available to VHA Headquarters upon request.

5.0 PROTOCOL REVIEW OUTCOMES

1) **Approval.** Full approval is granted to protocols that are approved by the SRS without the need for changes or additional information.

2) **Requires Minor Modifications to Secure Approval.** If the Committee's required modifications (to secure approval) are few in number and relatively insignificant in nature, i.e., failure to check a box on the form, failure to have the right drug dose, the investigator's response(s), i.e., modifications, may be reviewed using the designated-reviewer method to ensure that the modifications (to secure approval) are acceptable. The designated reviewer(s) can approve the protocol without further review unless a committee member, during or subsequent to the initial review by the full committee, requests full committee review of the investigator's response(s).

3) **Requires Significant Modifications to Secure Review.** If the required modifications (to secure approval) are of a more significant nature, the investigator must address all required modifications identified by the committee prior to approval and the entire committee reviews the modifications prior to the protocol being released for animal ordering.

4) **Withhold Approval.** If the SRS withholds approval of a proposal, it includes a statement of the reasons for its decision and gives the investigator an opportunity to respond.

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